



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0021]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Notification Procedure for Substances Generally Recognized as Safe (GRAS).

DATES: Submit either electronic or written comments on the collection of information by

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to

<http://www.regulations.gov>. Submit written comments on the collection of information to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Substances Generally Recognized as Safe: Notification Procedure--21 CFR 170.36 and 570.36
(OMB Control Number 0910-0342)--Extension

Section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348) establishes a premarket approval requirement for “food additives”; section 201(s) of the FD&C Act (21 U.S.C. 321(s)) provides an exclusion to the definition of “food additive” and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. In the Federal Register of April 17, 1997 (62 FR 18938), we published a proposed rule that would establish a voluntary procedure whereby manufacturers would notify us about a view of a particular use (or uses) of a substance is not subject to the statutory premarket approval requirements based on a determination that such use is GRAS. Under an interim policy announced in the proposed rule, we invited manufacturers to submit notices of their independent determinations for review under the framework of the proposed rule during the period between issuance of the proposal and any final rule based on the proposal. The proposed regulations (proposed 21 CFR 170.36 and 21 CFR 570.36) provide a standard format for the voluntary submission of a notice.

To assist respondents in submissions to our Center for Food Safety and Applied Nutrition (CFSAN), we developed Form FDA 3667 entitled “Generally Recognized as Safe Notice.” The form, and elements prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway (ESG), or may be submitted in paper format, or as electronic files on physical media with paper signature page. While we do not expect Form FDA 3667 to reduce reporting time for respondents, use of the form helps to expedite our review of the information being submitted. For submissions to our Center for Veterinary Medicine (CVM),

respondents may continue to send GRAS notices in letter format to the Agency, as instructed in our Federal Register notice of June 4, 2010 (75 FR 31800).

Presently, we have committed to issuing a final rule regarding “Substances Generally Recognized as Safe” in 2016, as part of a settlement agreement with the Center for Food Safety, which filed a lawsuit in 2014 seeking to vacate our 1997 proposed rule.

Description of Respondents: The respondents to this collection of information are manufacturers of substances used in food and feed.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Part	FDA Form No. ²	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
170.36 (CFSAN)	FDA 3667 ³	40	1	40	150	6,000
570.36 (CVM)	N/A	20	1	20	150	3,000
Total						9,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Only CFSAN uses Form FDA 3667.

³ Form FDA 3667 may be submitted electronically via the ESG.

Table 2.--Estimated Annual Recordkeeping Burden¹

21 CFR Part	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
170.36(c)(v) (CFSAN)	40	1	40	15	600
570.36(c)(v) (CVM)	20	1	20	15	300
Total					900

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

For purposes of this extension request, we are retaining our 2012 estimates. The PRA analysis for the GRAS final rule will take into account any changes to the GRAS notification procedure as set forth in the final rule and we will revise the collection accordingly.

Dated: September 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-23334 Filed: 9/16/2015 08:45 am; Publication Date: 9/17/2015]